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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,620	02/26/2002	Kate Loughney	27866/38275	4342

4743 7590 03/03/2003

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EXAMINER

HUTSON, RICHARD G

ART UNIT PAPER NUMBER

1652

DATE MAILED: 03/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/083,620

Applicant(s)

LOUGHNEY, KATE

Examiner

Richard G Hutson

Art Unit

1652

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- ☐ Interview Summary (PTO-413) Paper No(s). ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2, drawn to phosphodiesterase 10 (PDE10) polypeptide, classified in class 435, subclass 196.
- II. Claims 3-19, drawn to nucleic acid encoding phosphodiesterase 10, vectors and host cells comprising and methods of expressing, classified in class 435, subclass 196.
- III. Claims 20-23, drawn to phosphodiesterase 10 antibodies, classified in class 530, subclass 387.1.
- IV. Claims 24-27, drawn to methods of identifying PDE10 binding partners, classified in class 435, subclass 7.8.
- V. Claims 28-31, drawn to methods of identifying PDE10 polynucleotide binding partner, classified in class 435, subclass 6.
- VI. Claims 32-33, drawn to a compound identified by the methods of groups IV or V, classification unknown as the specification discloses no structural information for the claimed compound (Possible classifications could be class 260 (organic compounds), class 530 (proteins), class 536 (carbohydrates), class 423 (inorganic compounds) etc..) and a pharmaceutical composition comprising said compound, classified in class 514, subclass 789.

For each of inventions I-VI above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of inventions I-VI and one of inventions (A)-(D).

- (A). SEQ ID NO: 1 or a sequence encoding SEQ ID NO: 2.
- (B). SEQ ID NO: 18 or a sequence encoding SEQ ID NO: 19.
- (C). SEQ ID NO: 20 or a sequence encoding SEQ ID NO: 21.
- (D). SEQ ID NO: 22 or a sequence encoding SEQ ID NO: 23.

The inventions are distinct, each from the other because of the following reasons:

Inventions (A)-(D) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects.

The protein of group I, the nucleic acid of group II, the antibody of group III and the compound of group VI each comprise a chemically unrelated structure capable of separate manufacture, use and effect. The protein and antibody of groups I and III comprise an unrelated amino acid sequence, the nucleic acid of group II comprises nucleic acid sequence and the compound of group VI comprises a completely undefined chemical structure. The protein and antibody can be made by separate methods such

as isolation from natural sources or chemical synthesis and the protein has other utility besides acting as an antigen to induce the antibody, such as phosphodiesterase. The DNA has other utility besides encoding protein such as a hybridization probe, and the proteins can be made synthetically.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the PDE10 product of group I can be used to induce the antibodies of group III.

The nucleic acid of group II, the antibody of group III and the compound of group VI are unrelated to the method of group IV as they are neither used nor made by the method of group IV.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the PDE10 polynucleotide product of group II can be used to synthesize the PDE10 polypeptide of group I.

The polypeptide of group I, the antibody of group III and the compound of group VI are unrelated to the method of group V as they are neither used nor made by the method of group V.

The methods of groups IV and V are independent as they comprise different steps, utilize different products and produce different results.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. *"For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP 808.02."* (see MPEP 803). The serious burden of search has been established by the different classification and/or the different searches required for each of the inventions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Application/Control Number: 10/083,620

Art Unit: 1652

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Richard Hutson", written over a horizontal line.

Richard Hutson, Ph.D.
Patent Examiner
Art Unit 1652
February 24, 2003